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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,211	02/17/2004	Rainer Kuth	P03,0622	9905

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EXAMINER	
SEREBOFF, NEAL	
ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,211	KUTH ET AL.	
	Examiner	Art Unit	
	NEAL R. SEREBOFF	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/2009 has been entered.

Response to Amendment

2. In the amendment dated 3/17/2009, the following has occurred: Claims 2 – 7, 9 and 12 have been amended.

3. Claims 1 and 11 have been previously canceled. Claims 2 – 10 and 12 are pending.

Notice to Applicant

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 2 – 10 depend upon claim 12. For clarity, the rejection below of claim 12 precedes the rejections below of claims 2 – 10.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2 – 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "only and precisely" in claim 12 is a relative term

which renders the claim indefinite. The term "only and precisely" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Examiner is unsure whether "only and precisely" is used to modify the information being entered into the fields, to modify the fields presented or to modify a combination of the fields and the data. Claims 2 – 10 are rejected for the same reason as they depend upon claim 12.

8. Claims 3 and 6 recites the limitation "the electronically storable medical data standard" in second line of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. ***Claim 12*** is rejected under 35 U.S.C. 103(a) as being unpatentable over a piece of paper and a computer.

11. As per claim 12, a piece of paper teaches method to input and electronically store data for a medical clinical study, comprising the steps of:

- Distributing said customized input platform program to each of a plurality of computer workstations each having a display,
    - Respectively located input locations with which patients participating in the specific medical clinical study interface;
- Upon interfacing at one of said input locations with one of said patients,

- Entering a characteristic identifying that patient into the computer system workstation at said one of said input locations and,
- Via the computer workstation, automatically calling and activating said customized input platform program solely for said specific medical clinical study by entry of said characteristic into said computer workstation;

- Via said display of said computer workstation at said one of said input locations,
  - Providing data for said specific medical clinical study only by making entries in respective data input fields of the collection of input fields caused by said customized input platform program to be presented at the computer at the display of the computer workstation at the input location; and
- Electronically storing the data entered via the customized input platform program to generate an electronically accessible database for said customized input platform program and making said database electronically accessible to participants in said specific medical clinical study.

A piece of paper does not teach

- Generating a customized input platform program comprising programming instructions for operating a computer workstation having a display,
  - That cause a collection of input fields to be presented at said display that are configured only and precisely for entry of the data that is necessary for a specific medical clinical study;

However, a general purpose computer teaches

- Generating a customized input platform program comprising programming instructions for operating a computer workstation having a display,
    - That cause a collection of input fields to be presented at said display that are configured only and precisely for entry of the data that is necessary for a specific medical clinical study;

The piece of paper does not teach the electronic distribution of that piece of paper. The Examiner states that it would have been prima facie obvious to automate the piece of paper. The Examiner makes this statement in view of Oracle Remote Data Capture, Third Generation Systems, "An individual study may use a mixture of Remote Data Capture and paper-based collection, or data could be collected entirely on paper and the Remote Data capture system could be used purely for query resolution."
Additionally, as stated within the Applicant's remarks, dated 3/17/2009, "A person of ordinary skill in the field of implementing medical studies using electronic data entry would have no difficulty in understanding what data are necessary for a specific medical study, and therefore would have not difficulty in understanding, in turn, the scope and meaning of input fields that are configured only and precisely for entry of that data."

12. ***Claims 4, 10 and 12*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Oracle clinical research process suite, "Oracle Clinical" and "Oracle Remote Data Capture" (RDC) in view of Califano et al., U.S. Pre-Grant Publication 2003/ 0033168.

13. As per claim 12,

Oracle teaches a method to input and electronically store data for a medical clinical study, comprising the steps of:

- Generating a customized input platform program comprising programming instructions for operating a computer workstation having a display (Oracle Clinical, Customized Study Definitions),
    - That cause a collection of input fields to be presented at said display that are configured only and precisely for entry of the data that is necessary for a specific medical clinical study (Oracle Clinical, Customized Study Definitions);
- Distributing said customized input platform program to each of a plurality of computer workstations each having a display (RDC, Third Generation Systems, Internet distribution)
    - Respectively located input locations with which patients participating in the specific medical clinical study interface (RDC, User Interface Challenge)
- Via said display of said computer workstation at said one of said input locations,
    - Providing data for said specific medical clinical study only by making entries in respective data input fields of the collection of input fields caused by said customized input platform program to be presented at the computer at the display of the computer workstation at the input location (Oracle Clinical, Integrated Subsystems for Managing Clinical Data); and
- Electronically storing the data entered via the customized input platform program to generate an electronically accessible database for said customized input platform program

and making said database electronically accessible to participants in said specific medical clinical study (RDC, Figure: Typical architecture for third generation solution).

Oracle clinical research process suite does not explicitly teach the method comprising

- Upon interfacing at one of said input locations with one of said patients,
    - Entering a characteristic identifying that patient into the computer system workstation at said one of said input locations and,
    - Via the computer workstation, automatically calling and activating said customized input platform program solely for said specific medical clinical study by entry of said characteristic into said computer workstation;

However, Califano further teaches the method comprising

- Upon interfacing at one of said input locations with one of said patients,
    - Entering a characteristic identifying that patient into the computer system workstation at said one of said input locations (figure 11A, #316, login) and,
    - Via the computer workstation, automatically calling and activating said customized input platform program solely for said specific medical clinical study by entry of said characteristic into said computer workstation (figure 11A, #310);

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Oracle clinical research process suite. One of ordinary skill in the art at the time of the invention would have added these features into Oracle clinical research process suite

- With the motivation to provide a system and method for biomedical professionals to enroll participants into a study or procedure that they are conducting (Califano, paragraph 23).
- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable. When combined, the elements perform the same function as they did separately.

14. As per claim 4, Oracle clinical research process suite in view of Califano teaches the method of claim 12 as described above. Oracle clinical research process suite further teaches the method comprising electronically storing the data acquired at an input location in a data format that is determined by the customized input platform program (Oracle Clinical, Summary, RDC stores the data in a centralized database).

15. As per claim 9, Oracle clinical research process suite in view of Califano teaches the method of claim 12 as described above. Oracle clinical research process suite further teaches the method comprising, via said input platform, permitting only inputs into said collection of input fields that are required for said specific medical clinical study and that are incurred at the input locations that interface with patients participating in the specific medical clinical study (Oracle Clinical, Laboratory Reference Range Management).

16. As per claim 10, Oracle clinical research process suite in view of Califano teaches the method of claim 12 as described above. Oracle clinical research process suite further teaches the method comprising generating the customized input platform program by a research entity commissioning the specific medical clinical study (The Examiner notes that the "by a research entity commission the specific medical clinical study" represents non-functional descriptive

information. Changing the generator of the study from the claimed research entity to a outside agency does not change the method. Therefore, Oracle Clinical, Comprehensive Study Design and Management).

17. ***Claim 2, 3, 5 – 8*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Oracle clinical research process suite, "Oracle Clinical" and "Oracle Remote Data Capture" (RDC) in view of Califano et al., U.S. Pre-Grant Publication 2003/ 0033168, as applied to claim 12 above, further in view of Teshima, U.S. Patent Number 6,272,470.

18. As per claim 2 Oracle clinical research process suite in view of Califano teaches the method of claim 12 as described above.

Oracle clinical research process suite in view of Califano does not explicitly teach the method comprising distributing the customized input platform program in a framework of an electronically storable medical data standard.

However, Teshima further teaches the method comprising distributing the customized input platform program in a framework of an electronically storable medical data standard (column 1, lines 53 – 67 where the standard is DICOM where the platform is customized by adding the DICOM standard).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Oracle clinical research process suite in view of Califano. One of ordinary skill would have added this feature into Oracle clinical research process suite in view of Califano with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system

enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

19. As per claim 3, Oracle clinical research process suite in view of Califano teaches the method of claim 12 as described above.

Oracle clinical research process suite in view of Califano does not explicitly teach the method comprising electronically storing the customized input platform program in a region of the electronically storable medical data standard reserved for patient data.

However, Teshima further teaches the method comprising storing the customized input platform program in a region of the medical data standard reserved for patient data (column 3, lines 8 – 67 where the system is customized to operate on a portable input platform).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Oracle clinical research process suite in view of Califano. One of ordinary skill would have added this feature into Oracle clinical research process suite in view of Califano with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

20. As per claim 5, Oracle clinical research process suite in view of Califano teaches the method of claim 4 as described above.

Oracle clinical research process suite in view of Califano does not explicitly teach the method comprising electronically storing the acquired data in a framework of an electronically storable medical data standard.

However, Teshima further teaches the method comprising electronically storing the acquired data in a framework of an electronically storable medical data standard (column 14, lines 26 – 34 where the standard is DICOM).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Oracle clinical research process suite in view of Califano. One of ordinary skill would have added this feature into Oracle clinical research process suite in view of Califano with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

21. As per claim 6, Oracle clinical research process suite in view of Califano teaches the method of claim 4 as described above.

Oracle clinical research process suite in view of Califano does not explicitly teach the method comprising electronically storing the acquired data in a region of the electronically storable medical data standard reserved for patient data.

However, Teshima further teaches the method comprising electronically storing the acquired data in a region of the electronically storable medical data standard reserved for patient data (column 11, lines 8 – 45 where the patient card contains patient data).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Oracle clinical research process suite in view of Califano. One of ordinary skill would have added this feature into Oracle clinical research process suite in view of Califano with the motivation to solve the problem of the storage capacity of a portable storage unit, and to

provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

22. As per claim 7, Oracle clinical research process suite in view of Califano teaches the method of claim 4 as described above.

Oracle clinical research process suite in view of Califano does not explicitly teach the method comprising using the Digital Imaging and Communication in Medicine (DlCOM) standard as the electronically storable medical data standard.

However, Teshima further teaches the method comprising using the Digital Imaging and Communication in Medicine (DlCOM) standard as the electronically storable medical data standard (column 14, lines 26 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Oracle clinical research process suite in view of Califano. One of ordinary skill would have added this feature into Oracle clinical research process suite in view of Califano with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

23. As per claim 8, Oracle clinical research process suite in view of Califano teaches the method of claim 4 as described above.

Oracle clinical research process suite in view of Califano does not explicitly teach the method comprising distributing the customized input platform program in a framework of a medical data standard that is the Digital Imaging and Communication in Medicine (DICOM) standard. However, Teshima further teaches the method comprising distributing the customized input platform program in a framework of a medical data standard that is the Digital Imaging and Communication in Medicine (DICOM) standard (column 14, lines 26 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Oracle clinical research process suite in view of Califano. One of ordinary skill would have added this feature into Oracle clinical research process suite in view of Califano with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or OS (Teshima, column 3, lines 8 – 15).

Response to Arguments

24. Applicant's arguments, see 101 arguments, filed 3/17/2009, with respect to claims 2 – 10 and 12 have been fully considered and are persuasive. The 35 U.S.C. 101 rejections of claims 2 – 10 and 12 has been withdrawn.

25. Applicant's arguments, see 112, 1st paragraph arguments, filed 3/17/2009, with respect to claims 2 – 10 and 12 have been fully considered and are persuasive. The 35 U.S.C. 112, 1st paragraph rejections of claims 2 – 10 and 12 has been withdrawn. The Examiner further notes that the Applicants statement, "The word 'type,' as is clear from the context, was being used in a much more general sense as meaning 'informal content.'"

26. Applicant's arguments filed 3/17/2009 have been fully considered but they are not persuasive.

- Regarding the 35 U.S.C. 112, 2nd paragraph rejections of claims 2 – 10 and 12
  - The Applicant states, "The Examiner is correct that the phrase 'only and precisely' modifies the configuration of the input fields for data entry, and this is clearly understandable as meaning that those input fields will be specifically configured dependent on the specific clinical study in question, so that data that are not needed, permitted or relevant to that particular study will not be entered, because no input field is provided for such unneeded, unwanted or superfluous data."
  - Additionally, the Applicant states, "When an alternative interpretation is available that avoids ascribing such a trivial and meaningless definition of a claim term, it must be assumed that the Applicants did not intend the trivial and meaningless definition as long as a more meaningful and relevant definition/ interpretation is disclosed in the specification." The Examiner has never seen the Applicant's opinion stated within the MPEP and is unsure where to find this idea. Additionally, the Applicant does not define his terms but describes them with open examples. It is within the Applicant's skill to craft definitions that exclude and include desired options.
  - As the Applicant has not eliminated the option that "only and precisely" covers the input of data into fields and not the choice of data fields, the Examiner's 112, 2nd paragraph rejection stands.
- Regarding the 35 U.S.C. 102(b) rejection of claim 12 over Official Notice.

- The Examiner has changed the rejection from to a 103 rejection in view of a piece of paper with a computer. Therefore, the Applicant's arguments are moot. The Examiner, with his trivial 102(b) rejection had tried to help the Applicant by showing the difficulty in differentiating the instant application over the prior art. The change of the rejection to 103 is only meant to help the Applicant further understand that the Applicant's instant invention has a very high hurdle to overcome in view of the prior paper method and KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (2007).

- Regarding the 35 U.S.C. 102(e) rejection
  - The Applicant's arguments are moot as the rejection has changed.
- Regarding the 35 U.S.C. 103(a) rejection
  - The Applicant argues that the dependent claims are allowable for the reasons given for independent claim 12. Therefore, this argument is moot also.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Noble, U.S. Patent 6,729,882

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Prosys 1997 Business Proce3ss Framework

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-

1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. S./
Examiner, Art Unit 3626
4/17/2009

/Robert Morgan/
Primary Examiner, Art Unit 3626